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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,622	05/07/2002	Nicholas Bachynsky	HO-P01615WO0	1907
7590 05/09/2006			EXAMINER	
James J Napies 701 West 14th Street Texarkana, TX 75501			ROYDS, LESLIE A	
			ART UNIT	PAPER NUMBER
			1614	
DATE MAILED: 05/09/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action  
Before the Filing of an Appeal Brief**

Application No.

09/744,622

Applicant(s)

BACHYNSKY ET AL.

Examiner

Leslie A. Royds

Art Unit

1614

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 28 April 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☒ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: 58 and 60-63.  
Claim(s) rejected: 1-5, 7-14, 57 and 59.  
Claim(s) withdrawn from consideration: 55 and 56.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s) \_\_\_\_\_.  
13. ☒ Other: See Continuation Sheet.

Leslie A. Royds  
Patent Examiner  
Art Unit 1614

4 MAY 2006

Continuation of 3. NOTE: Applicant's after-final amendment proposes the cancellation of pending claims 1-5, 7-14 and 55-63 in lieu of newly added claims 64-99, drawn to methods for treating or diagnosing cancer (claims 64-75), methods for treating or diagnosing infections (claims 76-88) and method for treating or diagnosing infestations (claims 89-99) in a subject by administering an amount of a mitochondrial uncoupling agent sufficient to induce whole body intracellular hyperthermia in the subject

The proposed amendments raise new issues under 35 U.S.C. 112, second paragraph, insofar as the claims are drawn to broad limitations (i.e., "method for treating or diagnosing cancer", see claim 64; "method for treating or diagnosing infections", see claim 76, and "method for treating or diagnosing infestations", see claim 89), followed by narrow limitations (i.e., "wherein the cancer is selected from the group consisting of prostate carcinoma, glioblastoma multiforme, Kaposi's sarcoma, peritoneal carcinomatosis, and glioma", see claim 64; "wherein the infections result from *Borrelia burgdorferi*, *Mycobacterium leprae*, *Treponema pallidum*, HIV, Hepatitis C, Herpes virus or papillomavirus", see claim 76; and "wherein the infestation results from *Candida*, *Sporothrix schenckii*, *Histoplasma*, *paracoccidioides*, *Aspergillus*, *Leishmania*, malaria, *acanthamoeba* or cestodes", see claim 89).

Regarding such limitations, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961), *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948), and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

Furthermore, the newly added claims are drawn to limitations that were not searched or previously considered in the former claim set. In particular, it is noted that the claims are now drawn to methods for "treating or diagnosing" any one of cancer, infections or infestations. The former claims were drawn to methods for inducing whole body intracellular hyperthermia, of which such a method could be used for the treatment of cancer, infections or infestations. The presence of this new limitation to "diagnosing" was not previously searched or considered such that the scope of the proposed newly added claims is materially different that what was originally considered.

In addition, it is further noted that Applicant has presented 35 additional claims, but has cancelled only the 22 finally rejected claims. Please see Part (3)(d) above.

Regarding the remarks that Applicant has presented accompanying the proposed amendments, each of the remarks is directed to the fact that the objected and/or rejected claims have been cancelled and, thus, the objection or rejection should be withdrawn. However, for the reasons stated above, the claim amendments will not be entered and the claims remain rejected for the reasons of record as set forth in the final rejection of November 30, 2005. Applicant's attention is directed thereto. Insofar as Applicant has not presented any arguments regarding the traversal of each of the objections and rejections set forth in the final rejection, the rejections remain proper and are maintained.

For these reasons, the proposed amendments to the claims will not be entered. The claims remain objected to and/or rejected for the reasons previously set forth in the final rejection of November 30, 2005.

Continuation of 13. Other: Regarding Applicant's submission of the Information Disclosure Statement (IDS) of April 28, 2006, it is noted that the IDS was accompanied by the appropriate fee under 37 C.F.R. 1.17(p). However, Applicant has failed to proffer the certification as required under 37 C.F.R. 1.97(e) in order for the IDS to be considered. Accordingly, the IDS has not been entered or considered at the time.

Applicant's attention is directed to 37 C.F.R. 1.97(e), which states that the certification under 1.97(e) is a statement that (1) each item of information contained in the IDS was cited in a communication from a foreign patent office not more than 3 months prior to the IDS filing or (2) no item of information contained in the IDS was cited in a communication from a foreign patent office and, to the knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in the IDS was known to any individual designated in 37 C.F.R. 1.56(c) more than 3 months prior to the IDS filing.

Failure to file the appropriate certification under 37 C.F.R. 1.97(e) results in non-consideration of the IDS submission.

*Ardin H. Marschel* 5/5/06  
**ARDIN H. MARSCHEL**  
**SUPERVISORY PATENT EXAMINER**